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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,071	08/22/2003	Philip A. Swain	5673-66690-01	9609

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EXAMINER

STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	Application No. 10/647,071	Applicant(s) SWAIN ET AL.	
	Examiner Amber D. Steele	Art Unit 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 100-104, 109 and 111-124 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 100-104, 109 and 111-124 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/28/05</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____<br>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)<br>6) <input type="checkbox"/> Other: _____. |
|--|---|

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-99, 105-108, and 110 were canceled, claims 101-103 and 109 were amended, and new claims 111-124 were added in the amendment to the claims received on June 1, 2006.

Claims 100-104, 109, and 111-124 are currently pending and under consideration.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group I (claims 100-104) in the reply filed on June 1, 2006 is acknowledged. The traversal is on the ground(s) that a serious burden to search Groups I and III does not exist. This is found persuasive. Therefore, Group III is rejoined with Group I. However, applicants did not traverse the restriction of Groups II and IV. Therefore, the restriction requirement between Groups I, II, and IV is maintained.

The requirement is still deemed proper and is therefore made FINAL.

3. Applicant's election of CJ3 as the species of CJ in the reply filed on June 1, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, upon further consideration the species election is withdrawn.

### ***Priority***

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/414,971, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 08/414,971 does not disclose nicotine or the nicotine metabolites of present Figure 19.

The disclosure of the prior-filed application, Application No. 08/563,673, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. While Application No. 08/563,673 (U.S. Patent 5,760,184 mentions nicotine (please refer to Figure 6 and column 10, line 13), the specific nicotine metabolites of present Figure 19 are not disclosed.

Therefore, the priority date for claims 100-104, 109, 111-113, and 117-124 is November 28, 1995 and the priority date for claims 114-116 is September 30, 1996.

#### ***Information Disclosure Statement***

5. The information disclosure statement filed October 28, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that

portion which caused it to be listed. It has been placed in the application file, but the information referred to therein (e.g. art that is crossed out or lined through) has not been considered.

6. The information disclosure statement (IDS) submitted on October 28, 2005 was considered by the examiner (e.g. art with examiner's initials). The art was found in either U.S. Patent application 08/563,673, U.S. Patent application 08/720,487, or U.S. Patent application 08/414,971.

#### *Drawings*

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 18A and 18B are not described in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or **amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required** in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

8. The disclosure is objected to because of the following informalities: The description for Figure 4 is embedded in the text of the description for Figure 3b.

Appropriate correction is required.

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Objections***

10. Claims 114-116 are objected to because of the following informalities: Claims 114-116 recite that the hapten is derived from nicotine or nicotine metabolites with the structures depicted in Fig. 19. Fig. 19 should be replaced with the names or the structures of the molecules in Fig. 19 since several molecules are shown in Fig. 19. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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12. Claims 100-103, 111, and 114-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Walling et al. U.S. Patent 5,164,504 issued November 17, 1992.

For present claim 100, Walling et al. teach cotinine (e.g. nicotine derivative/metabolite) hapten-carrier conjugates wherein the hapten is cotinine which is a metabolite of nicotine, the carrier can be a protein or a peptide including poly(amino acid), bovine serum albumin, albumin, serum protein, keyhole limpet hemocyanin, egg ovalbumin, bovine gamma globulin, thyroxine binding globulin, and polylysine (e.g. T-cell epitopes), and the carrier is covalently bound to the hapten via direct linkage (e.g. CJ 0) or (CH<sub>2</sub>)<sub>2</sub>CONH (e.g. CJ 6) (please refer to the Abstract; Formulas I, IV, V, VI, , VII, VIII, IX, X, XI, XII, XV, and XVI; columns 1-8; Examples 1-8; claims 1-6).

For present claim 101, Walling et al. teach  $n = 2$  and  $n = 0$  or 1 (please refer to Examples 6-7; Formulas XV and XVI; columns 2-6).

For present claim 102, Walling et al. teach utilizing S, O, and NH molecules in the branches joining the hapten and the carrier (please refer to columns 2-6).

For present claim 103, Walling et al. teach carriers that are proteins or peptides (please refer to columns 2-6).

For present claim 111, Walling et al. teach carriers that are proteins or peptides (please refer to columns 2-6).

For present claim 114, Walling et al. teach cotinine as nicotine metabolites (please refer to Formulas I, IV, V, VI, , VII, VIII, IX, X, XI, XII, XV, and XVI; columns 1-8; Examples 1-8; claims 1-6).

For present claim 115, Walling et al. teach cotinine as nicotine metabolites (please refer to Formulas I, IV, V, VI, VII, VIII, IX, X, XI, XII, XV, and XVI; columns 1-8; Examples 1-8; claims 1-6).

Therefore, the presently claimed invention is anticipated by the teachings of Walling et al.

13. Claims 100, 103, and 114 are rejected under 35 U.S.C. 102(e) as being anticipated by Manian et al. U.S. Patent 5,843,680 filed April 19, 1995.

For present claim 100, Manian et al. teach nicotine hapten-carrier conjugates wherein the carriers are polypeptides (e.g. T-cell epitope) and the carrier is directly linked to the hapten (e.g. CJ 0; please refer to columns 4-6, particularly column 5, line 12).

For present claim 103, Manian et al. teach that the carries can be polypeptides (please refer to column 6, lines 52-60).

For present claim 114, Manian et al. teach nicotine as the hapten (e.g. structure in present Figure 19; please refer to column 4, lines 43-67 and column 5, lines 1-12).

Therefore, the presently claimed invention is anticipated by the teachings of Manian et al.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*



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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 100-104, 109, and 111-124 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-5, 8-12, and 17-18 of U.S. Patent No. 5,876,727. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions as claimed in U.S. Patent No. 5,876,727 claim nicotine or nicotine-derived haptens conjugated to a carrier and pharmaceutical compositions of the hapten-carrier.

For present claim 100, U.S. Patent No. 5,876,727 claims a nicotine hapten-carrier conjugate comprising the structure shown in Fig. 17b (e.g. nicotine derivative hapten) and side chains (e.g. branch) of CJ0 (for example Q), 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, 11 (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claim 1).

For present claim 101, U.S. Patent 5,876,727 claims n is from 3 to 20 (e.g. within the range of about 2 to about 20; please refer to claim 1).

For present claim 102, U.S. Patent 5,876,727 claims Y (e.g. for the CJ structures) is S, O, or NH (please refer to claim 1).

For present claim 103, U.S. Patent 5,876,727 claims carriers of cholera toxin, diphtheria toxin, tetanus toxoid, pertussis toxin, ricin B subunit, retrovirus nucleoprotein, rabies

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ribonucleoprotein, tobacco mosaic virus, or vesicular stomatis virus nucleocapsid protein (e.g. proteins, peptides, bacterial toxins, subvirals; please refer to claim 1).

For present claim 104, U.S. Patent 5,876,727 claims at least two haptens coupled to the carrier (e.g. greater than one hapten; please refer to claim 2).

For present claim 109, U.S. Patent 5,876,727 claims a pharmaceutically acceptable carrier, an aqueous solution at a physiologically acceptable pH, and adjuvants (e.g. pharmaceutically acceptable excipient; please refer to claims 8-11).

For present claim 111, U.S. Patent 5,876,727 claims carriers of cholera toxin, diphtheria toxin, tetanus toxoid, pertussis toxin, ricin B subunit, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, or vesicular stomatis virus nucleocapsid protein (e.g. proteins, peptides, bacterial toxins, subvirals; please refer to claim 1).

For present claim 112, U.S. Patent 5,876,727 claims carriers of cholera toxin, diphtheria toxin, tetanus toxoid, pertussis toxin, ricin B subunit, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, or vesicular stomatis virus nucleocapsid protein (please refer to claim 1).

For present claim 113, U.S. Patent 5,876,727 claims carriers of cholera toxin, diphtheria toxin, tetanus toxoid, pertussis toxin, ricin B subunit, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, or vesicular stomatis virus nucleocapsid protein (please refer to claim 1).

For present claim 114, U.S. Patent 5,876,727 claims nicotine of the structure of Fig. 17b (e.g. nicotine or nicotine metabolites; please refer to claim 1).

For present claim 115, U.S. Patent 5,876,727 claims nicotine of the structure of Fig. 17b (e.g. nicotine or nicotine metabolites; please refer to claim 1).

For present claim 116, U.S. Patent 5,876,727 claims nicotine of the structure of Fig. 17b (e.g. nicotine or nicotine metabolites; please refer to claim 1).

For present claim 117, U.S. Patent 5,876,727 claims adjuvants (please refer to claims 9-10).

For present claim 118, U.S. Patent 5,876,727 claims alum, MF59, or RIBI adjuvants (please refer to claims 9-10).

For present claim 119, U.S. Patent 5,876,727 claims the alum genus (e.g. aluminum hydroxide or aluminum phosphate; please refer to claims 9-10).

For present claim 120, U.S. Patent 5,876,727 claims pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. auxiliary agent or supplementary active compound; please refer to claims 8-11).

For present claim 121, U.S. Patent 5,876,727 claims parenteral administration to a mammal (e.g. human; please refer to claims 12 and 17).

For present claim 122, U.S. Patent 5,876,727 claims oral administration (please refer to claims 12 and 18).

For present claim 123, U.S. Patent 5,876,727 claims pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. excipient; please refer to claims 8-11).

For present claim 124, U.S. Patent 5,876,727 claims adjuvants (please refer to claims 9-10).

Therefore, the claims of U.S. Patent 5,876,727 render the present claims unpatentable.

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16. Claims 100-104, 109, and 111-124 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 43-45, 47-50, 52-54, 56-65, and 74-82 of copending Application Nos. 11/066,718; 11/472,215; 11/472,216; 11/472,217; 11/472,218; 11/472,219; 11/472,220; 11/472,222; and 11/472,223. Please note that the previously mentioned Patent Applications contain the same or similar claim sets, therefore, a single provisional nonstatutory obviousness-type double patenting rejection is being made for all of the applications. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions claimed in U.S. Patent applications 11/066,718; 11/472,215; 11/472,216; 11/472,217; 11/472,218; 11/472,219; 11/472,220; 11/472,222; and 11/472,223 (referred to as simply U.S. Patent Applications) claim hapten-carrier conjugates and pharmaceutical compositions.

For present claim 100, U.S. Patent Applications claim a nicotine hapten-carrier conjugate comprising the structure shown in Fig. 17b (e.g. nicotine derivative hapten) and branches of CJ0 (for example Q), 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, 11 (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claims 43 and 65).

For present claim 101, U.S. Patent Applications claim n is from 3 to 20 (e.g. within the range of about 2 to about 20; please refer to claims 43 and 65).

For present claim 102, U.S. Patent Applications claim Y (e.g. for the CJ structures) is S, O, or NH (please refer to claims 43 and 65).

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For present claim 103, U.S. Patent Applications claim carriers of proteins, peptides, multiantigenic peptides, cholera toxin, diphtheria toxin, tetanus toxoid, pertussis toxin, pertussis filamentous hemagglutinin, shiga toxin, ricin B subunit, abrin, sweet pea lectin, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, cow pea mosaic virus, cauliflower mosaic virus, vesicular stomatitis virus nucleocapsid protein, recombinant pox virus subunits and vectors, Semliki forest virus vectors, Pseudomonas endotoxin, multiantigenic peptides (MAP), yeast virus-like particles (VPLs), malarial protein antigen, and microspheres (please refer to claims 47-50).

For present claim 104, U.S. Patent Applications claim at least one or at least two haptens coupled to the carrier (please refer to claims 44-45 and 53-54).

For present claim 109, U.S. Patent Applications claim a pharmaceutically acceptable excipient (please refer to claim 56).

For present claim 111, U.S. Patent Applications claim carriers of proteins, peptides, multiantigenic peptides, cholera toxin, diphtheria toxin, tetanus toxoid, pertussis toxin, pertussis filamentous hemagglutinin, shiga toxin, ricin B subunit, abrin, sweet pea lectin, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, cow pea mosaic virus, cauliflower mosaic virus, vesicular stomatitis virus nucleocapsid protein, recombinant pox virus subunits and vectors, Semliki forest virus vectors, Pseudomonas endotoxin, multiantigenic peptides (MAP), yeast virus-like particles (VPLs), malarial protein antigen, and microspheres (e.g. bacterial toxins, subvirals, allergens; please refer to claims 47-50).

For present claim 112, U.S. Patent Applications claim carriers of cholera toxin, diphtheria toxin, tetanus toxoid, pertussis toxin, pertussis filamentous hemagglutinin, shiga toxin,

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*Pseudomonas* endotoxin, ricin B subunit, abrin, sweet pea lectin, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, cauliflower mosaic virus, vesicular stomatitis virus nucleocapsid protein, recombinant pox virus subunits and vectors, Semliki forest virus vectors, yeast virus-like particles (VPLs) (please refer to claims 47-50).

For present claim 113, U.S. Patent Applications claim carriers of cholera toxin, diphtheria toxin, tetanus toxoid, pertussis toxin, pertussis filamentous hemagglutinin, shiga toxin, *Pseudomonas* endotoxin, ricin B subunit, abrin, sweet pea lectin, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, cauliflower mosaic virus, vesicular stomatitis virus nucleocapsid protein, recombinant pox virus subunits and vectors, Semliki forest virus vectors, yeast virus-like particles (VPLs) (please refer to claims 47-50).

For present claim 114, U.S. Patent Applications claim nicotine of the structure of Fig. 17b (e.g. nicotine or nicotine metabolites; please refer to claims 43 and 65).

For present claim 115, U.S. Patent Applications claim nicotine of the structure of Fig. 17b (e.g. nicotine or nicotine metabolites; please refer to claims 43 and 65).

For present claim 116, U.S. Patent Applications claim nicotine of the structure of Fig. 17b (e.g. nicotine or nicotine metabolites; please refer to claims 43 and 65).

For present claim 117, U.S. Patent Applications claim adjuvants (please refer to claims 58-59).

For present claim 118, U.S. Patent Applications claim alum, MF59, or RIBI adjuvants (please refer to claims 58-59).

For present claim 119, U.S. Patent Applications claim the alum genus (e.g. aluminum hydroxide or aluminum phosphate; please refer to claims 58-59).

For present claim 120, U.S. Patent Applications claim pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. auxiliary agent or supplementary active compound; please refer to claims 56-60 and 74).

For present claim 121, U.S. Patent Applications claim parenteral administration to a mammal (e.g. human; please refer to claims 61-64, 75-79, and 81).

For present claim 122, U.S. Patent Applications claim oral administration (please refer to claims 80 and 82).

For present claim 123, U.S. Patent Applications claim pharmaceutically acceptable excipient (please refer to claim 56).

For present claim 124, U.S. Patent Applications claim adjuvants (please refer to claims 58-59).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,232,082 Ennifar et al. issued May 15, 2001 (filed December 1, 1998) discloses and claims nicotine hapten-carrier conjugates.

### ***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS

August 11, 2006



MARK SHIBUYA, PH.D.  
PATENT EXAMINER